Purged: 8/19/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 15 1997

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Roland Allgaier
Owner
Allgaier Instrumente GmbH
Teuchelgrube 6-10
D-78665 Frittlingen/Tuttlingen, Germany

Dear Mr. Allgaier:

During an inspection of your firm located in Tuttlingen, Germany, on May 26 through May 28, 1997, our Investigator determined that your firm manufactures stainless steel surgical instruments such as tweezers, chisels, knives, and forceps. These instruments are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) regulations of 1978, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 GMP regulation was superseded on June 1, 1997, by the Current Good Manufacturing Practice (CGMP) requirements as set forth in the Quality System Regulation, 21 CFR 820. The deficiencies noted during the inspection reference the 1978 GMP requirements with a cross reference to the new 1997 Quality System Regulation.

1. Failure to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications, as required by 21 CFR 820.198(b). This would also be a violation of the Quality System Regulation, 21 CFR 820.198(c). For example, complaints of rust spots were not investigated to determine the cause of the rust spots. The following complaint numbers reported the appearance of rust spots on devices:

   Your responses dated June 30, 1997, and July 4, 1997, may be adequate if you provide an English translation of the summary of complaint statistics for our review.

2. Failure of the quality assurance program to identify, recommend or provide solutions for quality assurance problems and verify the implementation of such solutions, as required by 21 CFR 820.20(a)(3). This would also be a violation of the Quality System Regulation, 21 CFR 820.100. For example, investigations were not made to determine the cause of rust spots occurring on devices identified in complaints

   Your responses dated June 30, 1997, and July 4, 1997, may be adequate if you provide an English translation of the summary of complaint statistics for our review.

3. Failure to adequately investigate any failure of a device to meet performance specifications after the device has been released for distribution, as required by 21 CFR 820.162. This would also be a violation of the Quality System Regulation, 21 CFR 820.100. For example, investigations were not conducted to determine the cause of rust spots on devices returned under Complaint numbers

   Your responses dated June 30, 1997, and July 4, 1997, may be adequate if you provide an English translation of the summary of complaint statistics for our review.

4. Failure to establish and implement specification control measures to assure that the design basis for the device and packaging is correctly translated into approved specifications, as required by 21 CFR 820.100(a)(1). This would also be a violation of the Quality system Regulation, 21 CFR 820.30(h) and 21 CFR 820.75. For example:

   a. The [redacted] and [redacted] processes have not been validated to determine if the processes and [redacted] are adequate to prevent rusting on the devices.

   Your responses dated June 30, 1997, and July 4, 1997, are adequate.

   b. The [redacted] process has not been validated.

   Your response may be adequate if you provide an English translation of the validation protocol and results of the validation study of the [redacted] process.

5. Failure to have written procedures describing any processing controls necessary to assure conformance to specifications, where deviations from device specifications could occur as a result of the manufacturing process itself, as required by 21 CFR 820.100(b)(1). This would also be a violation of the Quality System Regulation, 21 CFR 820.70(a). For example:

   a. There is no written procedure to identify which forging lots or production lots are tested for [redacted] during manufacturing. Lot numbers [redacted] were not tested for [redacted].

Your responses dated June 30, 1997, and July 4, 1997, are adequate.

   b. The procedure specifying the concentration of the [redacted] is not consistent with the concentration specified in the [redacted] procedure. For example, the [redacted] procedure calls for the use of [ ] liters of the [redacted] while the [redacted] procedure calls for the use of [ ] liters of the [redacted].

Your response may be adequate if you provide an English translation of the [redacted] procedure, and the [redacted] procedure for our review.

6. Failure to conduct processing control operations in a manner designed to assure that the device conforms to applicable specifications, as required by 21 CFR 820.100(b)(2). This would also be a violation of the Quality System Regulation, 21 CFR 820.70(a). For example, the [redacted] procedure does not specify the [redacted], or the [redacted] required for each type of steel during [redacted] of the [redacted] [redacted] process.

Your responses dated June 30, 1997, and July 4, 1997, may be adequate if you provide an English translation of the test report and the [redacted] procedure entitled [redacted] for our review.

7. Failure to subject any change in the manufacturing process of a device to a formal approval process, as required by 21 CFR 820.100(b)(3). This would also be a violation of the Quality System Regulation, 21 CFR 820.70(b). For example:

a. The change from the use of the [redacted] to the current [redacted], was not documented or signed off by a designated individual.

Your responses dated June 30, 1997, and July 4, 1997, are adequate.

b. A change of the [redacted] specifications for [redacted] dimensions was not documented, approved, or signed off by a designated individual. For example, [redacted] Program [redacted] shows an initial value of [redacted], and [redacted] Program [redacted] shows an increased [redacted] value of [redacted] for the same type of instruments.

Your responses dated June 30, 1997, and July 4, 1997, are adequate.

8. Failure to base sampling plans for checking, testing, and release of a device on an acceptable statistical rationale, as required by 21 CFR 820.160. This would also be a violation of the Quality System Regulation, 21 CFR 820.80(d). For example, the production records for lot [redacted] ([redacted] pieces), lot [redacted] ([redacted] pieces), and lot [redacted] ([redacted] pieces) contain [redacted] results; however, the number of samples tested per lot, or the sampling criterion is not specified or documented.

Your responses dated June 30, 1997, and July 4, 1997, are adequate.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

The specific violations noted in this letter and the form FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

We acknowledge that you have submitted two letters dated June 30, 1997, and July 4, 1997, concerning our Investigator's observations noted on the form FDA 483. We have reviewed your responses and have concluded that while some of the responses are adequate, we were not able to evaluate you responses "in toto" because many of the documents you provided were not translated from German to English. Detailed comments on your responses are cited above.

Given the serious nature of these violations of the Act, all devices manufactured by Allgaier Instrumente GmbH, Tuttlingen, Germany, may be detained upon entry into the United States without physical examination until these violations are corrected. In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that your response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office, in writing, within 15 days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, HFZ-323, 2098 Gaither Road, Rockville, Maryland, 20850, to the attention of Peggy C. Mayo.

Sincerely yours,

for Jeffrey R. Kirk

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health